

REMARKS

Claims 1-11, 15, 17-18, 27-28 and 35 are amended herein and claim 14 is canceled. Claims 23-26 and 29-31 were previously canceled. Upon entry of the Amendment, claims 1-13, 15-22, 27-31 and 35 will be all of the claims pending in the application. Of these, claims 19-22 and 29-31 are withdrawn as being drawn to a nonelected invention.

No new matter is presented.

I. Response to Claim Objections

Claims 17 and 18 are objected to because of the phrase “is sustained release formulation”.

Claims 17 and 18 are amended herein to recite “. . . which is a sustained release formulation . . .” to correct an inadvertent typographical error, thereby obviating the objection.

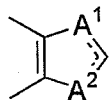
Withdrawal of the objection is respectfully requested.

II. Response to Claim Rejections - 35 U.S.C. § 112

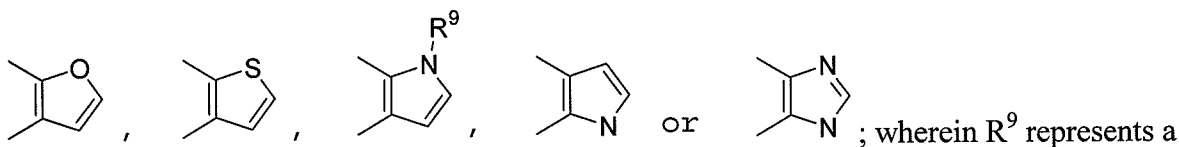
1. Claims 1-18, 27-28 and 35 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite as follows.

Claim 1 is said to be indefinite allegedly because the symbols or letters A1 and A2 in the general formula (I) are not defined in the claim.

Applicants respectfully traverse and submit that the meaning and scope of the claim is readily ascertainable to those of ordinary skill in the art. Claim 1 recites ring:



represents



hydrogen atom, a C₁₋₆ alkyl group, a hydroxy(C₁₋₆ alkyl) group, a C₃₋₇ cycloalkyl group or a C₃₋₇ cycloalkyl(C₁₋₆ alkyl) group.

Thus, A¹ and A² are sufficiently defined in context of the identified rings.

Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 14 and 15 recite the phrase “a disease associated with hyperglycemia”, which the Examiner states is indefinite because it is unclear what constitutes or does not constitute an association as recited in the claims.

Claim 14 is canceled herein, thereby rendering the rejection as to claim 14 moot.

Applicants traverse the rejection with respect to claim 15, since claim 15 clearly recites specified diseases associated with hyperglycemia. In this connection, claim 15 is amended to depend from claim 11.

Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 17 recites the phrase “A pharmaceutical composition as claimed in claim 10, wherein the dosage form is sustained release formulation”, which the Examiner states is indefinite because it is unclear whether a dosage form is claimed or a pharmaceutical composition in a dosage form. Furthermore, the Examiner states that it is unclear how the dosage form differs from the pharmaceutical composition that is not in a dosage form, especially since the characteristics of said dosage form with respect to amounts, quantities are unknown. Moreover the Examiner states that it is unclear what method or process involves a sustained

release of said composition and if said composition must be tested in said process in order to practice Applicants' invention.

Claim 17 is amended herein for clarity to recite "The pharmaceutical composition as claimed in claim 10, which is a sustained release formulation". The term "sustained release formulation" is well known in the art and defines formulations having extended or sustained release profiles over other non-sustained release formulations. Thus, the meaning and scope of the claim language is readily understood by those of ordinary skill in the art.

Claim 18 recites the phrase "A human SGLT inhibitor as claimed in claim 11, wherein the dosage form is sustained release formulation". The Examiner states that the claim is indefinite since it is unclear whether a dosage form is claimed or a human SGLT inhibitor in a dosage form. Furthermore, the Examiner states that it is unclear how the dosage form differs from the human SGLT inhibitor (composition) that is not in a dosage form, especially since the characteristics of said dosage form with respect to amounts or quantities are unknown. Moreover, the Examiner states that it is unclear what method or process involves a sustained release of said composition and if said composition must be tested in said process in order to practice Applicants' invention.

Claim 18 is amended herein for clarity to recite "The human SGLT inhibitor as claimed in claim 11, which is a sustained release formulation". Additionally, the term "sustained release formulation" is well known in the art as discussed above.

Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 27 and 28 are said to be indefinite with respect to the terms "carnitine derivative", "nicotinic acid derivative", "a glucagon-like peptide-1 analogue", "an amylin analogue" and "a platelet-derived growth factor analogue".

Claims 27 and 28 are amended by deleting the terms mentioned above, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection.

2. **Claims 14 and 15** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a composition or agent for treating specific diseases such as obesity or diabetes in a patient, allegedly does not reasonably provide enablement for preventing said diseases including obesity or diabetes in a patient.

Claim 14 is canceled herein, thereby rendering the rejection moot as to this claim.

Claim 15 is amended herein to depend from claim 11 and to recite, “which is an agent for the treatment of a disease . . .”, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection.

3. **Claims 27 and 28** are rejected under 35 U.S.C. §112, first paragraph, for scope of enablement because the specification, while being enabling for a pharmaceutical composition as claimed in claim 10, which comprises a combination with specific substances or compounds such as acarbose and voglibose, allegedly does not reasonably provide enablement for a pharmaceutical composition as claimed in claim 1.

Applicants traverse the rejection. The specification provides several examples of the different types of agents and sufficient guidance in view of the knowledge and skill in the art for making a composition comprising a combination of the compounds of formula (I) and the agents specified in the claims (please see pages 72-94 of the specification as filed). Thus, the claims are sufficiently enabled such that one of ordinary skill in the art can practice the full scope of the invention without undue experimentation.

Accordingly, Applicants respectfully request withdrawal of the rejection.

4. **Claims 1-18, 27-28 and 35** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a fused heterocyclic derivative represented by the following general formula (I) or pharmaceutically acceptable salt thereof, or a specific prodrug of general formula (I) denoted by structure, allegedly does not reasonably provide enablement for any prodrug of the general formula (I).

The claims are amended herein by deleting references to prodrugs, thereby obviating the rejection.

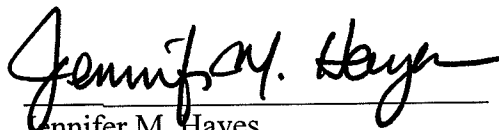
Accordingly, Applicants respectfully request withdrawal of the rejection.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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CUSTOMER NUMBER

Date: September 21, 2010